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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,907	02/17/2004	Robert D. Black	9099-18	8994

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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/779,907	BLACK ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-104 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-104 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 – 30, drawn to a method for determining the *in vivo* clinical efficacy of a treatment in a subject, classified in class 424, subclass 9.2.

II. Claims 31 – 42, drawn to a method of evaluating a subject, classified in class 600, subclass 300.

III. Claims 43 – 69, drawn to a detection system for detecting fluorescence in a subject, classified in class 424, subclass 9.6.

IV. Claims 70 – 88, drawn to an implantable fluorescence sensor, classified in class 422, subclass 82.08.

V. Claims 89 – 104, drawn to a computer program product for evaluating a subjects *in vivo* response, classified in class 700, subclass 1.

NOTE: In addition to the elected Group above, if Group I is elected, applicant is requested to elect a *specific* analyte from the distinct group thereof as set forth in the claims (e.g. claim 1, 10, 11, or 12) to which the search for the elected Group will be limited. The different actions included therein are a very diverse set and are independent and distinct actions, including a fluorescently pre-labeled analyte, a naturally fluorescent analyte, an analyte that exhibits fluorescence when internally administered, a therapeutic pharmaceutical drug, an antibody, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

In addition to the elected Group above, if Group I is elected, applicant is requested to elect a *specific* action related to the monitoring step from the distinct group thereof as set forth in the claims (e.g. claim 1, 10, 11, 12, 13, 15, 17, 18, 19, 20, 27 or 30) to which the search for the elected Group will be limited. The different actions included therein are a very diverse set and are independent and distinct actions, including predicting *in vivo* clinical efficacy, measuring the localized dose, adjusting the therapeutic dose amount administered, determining uptake and retention of fluorescent analyte in a localized region, serially determining the fluorescent intensity of the fluorescent analyte in localized tissue at a plurality of points in time and determining a pharmacokinetic response, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

In addition to the elected Group above, if Group II is elected, applicant is requested to elect a *specific* action related to using the data associated with the detected fluorescence from the distinct group thereof as set forth in claim 31 to which the search for the elected Group will be limited. The different actions included therein are a very diverse set and are independent and distinct actions, including confirming Ab attachment to a tumor site, monitoring expression of a protein, etc., which control the classification, thus, necessitate a specific election to which the elected Group will be drawn.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs because the method of evaluating a subject requires steps of using data associated with the detected fluorescence intensity to perform steps of calculating the concentration or dose of analyte received, confirming Ab attachment to a site, monitoring expression of a protein, etc., which the method of determining the *in vivo* clinical efficacy of a treatment in a subject does not.

Inventions I – II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, inventions have different designs because the processes of determining *in vivo* clinical efficacy of a treatment and of evaluating a subject as claimed do not require the use of a processor.

Inventions I – II and IV are related as processes of use and a product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the processes can be practiced with another materially different product. For example, a method for determining *in vivo* efficacy of a treatment can be practiced with various activity assays, etc.

Inventions I – II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions have different designs and modes of operation because the processes of determining *in vivo* clinical efficacy of a treatment and of evaluating a subject as claimed do not require the use of a computer program.

Inventions III and IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a materially different design because a materially different sensor may be an LED, for example.

Inventions III and V are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a different mode of operation or function because a computer program can be used for directing or monitoring another medical device, such as an EKG, for example.

This application contains claims directed to distinct species related to the analyte in a method for determining *in vivo* clinical efficacy of a treatment in Group I (i.e. a fluorescently pre-labeled analyte, a naturally fluorescent analyte, an analyte that exhibits fluorescence when internally administered, a therapeutic pharmaceutical drug, an antibody, etc.). The species are independent or distinct because of their different functions and effects.

This application contains claims directed to distinct species related to the monitoring step in a method for determining *in vivo* clinical efficacy of a treatment in Group I (i.e. predicting *in vivo* clinical efficacy, measuring the localized dose, adjusting the therapeutic dose amount administered, determining uptake and retention of fluorescent analyte in a localized region, serially determining the fluorescent intensity of the fluorescent analyte in localized tissue at a plurality of points in time and determining a pharmacokinetic response, etc). The species are independent or distinct because of their different functions and effects.

This application contains claims directed to distinct species related to using the data associated with detected fluorescence in the method of evaluating a subject in Group II (i.e. confirming Ab attachment to a tumor site, monitoring expression of a protein, etc.). The species are independent or distinct because of their different functions and effects.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

A telephone call was not made to request an oral election to the above restriction requirement because of the complexity of the restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. NOTE: This disclosed species will name a single specific analyte and monitoring step if the invention of Group I is elected and a single specific action associated with using data associated with the detected fluorescence if the invention of Group II is elected. An exemplified species should be elected to show clear support in the specification for the elected species.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Notice of Potential Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lhs

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER